Sentara Norfolk General
Norfolk, VA

POLYHEME CLINICAL TRIAL
Community Consultation and Civic League Meetings
Agenda

I. Patient presentation: Dr. Leonard Weireter or Dr. Jon Mason

II. What is Polyheme? Dr. Leonard Weireter or Dr. Jon Mason

III. Are you a Candidate for Polyheme? Lynn Hopkins James

IV. Purpose of Public Disclosure and the consent process: Lynn Hopkins James

IV. Questions /Answers and Feedback Evaluations

QUESTIONS AND ANSWERS
POLYHEME® TRAUMA TRIAL

Why is this study being conducted?

To evaluate the life-saving potential of PolyHeme® when given to severely injured patients and bleeding patients, starting at the scene of injury

What is the title of this study?

A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection [Polymerized Human Hemoglobin (Pyridoxylated) PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting

What is the design of this study?

Patients in "hemorrhagic shock" will begin to receive either the standard of care (salt water) (control) or PolyHeme (investigational treatment). Treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12 hour postinjury period in the hospital.

In the hospital, patients in the control group will receive salt water for hydration and blood if necessary to boosts oxygen levels. Unlimited doses of each are allowed.

Patients in the treatment group will receive salt water for hydration and PolyHeme® to boost oxygen levels. The maximum dose of PolyHeme will be 6 units during first 12 hours. Blood will be used thereafter.

What is hemorrhagic shock?

Hemorrhagic means the patient has experienced massive blood loss
Shock is a life-threatening condition that might include:

- *Dangerously low blood pressure*
- *Internal organs don't receive enough oxygen and have difficulty functioning*
- *Might lead to death*

Why is there a need for improvement in the way trauma patients are treated now?

Trauma is the leading cause of death among Americans under the age of 45.

What is the current standard of care? How are trauma patients usually treated?

They are given saline solution (salt water) at the scene or in the ambulance. When they arrive at the hospital, they are given blood after typing and cross-matching is accomplished.

Who would be eligible for the study?

Patients who have lost a large amount of blood and are in shock
Patients who are at least 18 years old
Patients who have sustained severe injuries

Who would be excluded from the study?

Women who are obviously pregnant
Patients with severe brain injuries
Patients who require CPR to maintain their heartbeat
Patients with "unsurvivable" injuries
Patients who are known to object to blood transfusions
Patients who are known to refuse resuscitation

What is PolyHeme®?

PolyHeme® is *an oxygen-carrying blood substitute made from human blood. PolyHeme® requires no cross-matching, therefore it is immediately available and compatible with all blood types. PolyHeme® is highly purified to reduce the risk of viral disease transmission. It has an extended shelf-life of over 12 months.*

Is PolyHeme® safe?

In clinical trials to date, PolyHeme® has demonstrated no clinically relevant adverse effects.

Past studies have shown that PolyHeme® carries as much oxygen as blood, has not caused organ damage, keeps people alive who have lost all of their own blood, and can be infused up to two times a person's entire blood volume.

Has PolyHeme® been tested on humans before?

There have been 5 human clinical trials of PolyHeme®.

How many patients have been treated with PolyHeme®?

Over 300 patients have been treated, including patients in a hospital-based trauma trial.

What happened to them?

In the Phase II hospital trauma trial, PolyHeme® significantly increased survival compared with historical controls.

What is an exception from informed consent?

Regulations established by the Federal government, (21 Code of Federal Regulations 50.24) specifies the conditions under which an exception from informed consent so that in emergency situations, research can be carried out even when consent is not possible because of the nature and extent of the patient's injuries.

Why was such an exception be granted in connection with this study?

Patients are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions.

Participating in the study has the prospect of direct benefit to the enrolled patients because:

- *Patients are in a life-threatening situation that necessitates intervention*
- *Previous studies demonstrate the potential to provide a direct benefit to enrolled patients*
- *Risks associated with the use of the PolyHeme® are reasonable in relation to what is known about the patients' medical condition, the risks and benefits of standard therapy, and the risks and benefits of the proposed intervention*

It is expected that patients will be unable to give informed consent because the extent of their injuries and the fact that they are in shock.

There won't be time to find and ask for consent from the patient's legally authorized representative (LAR) before beginning treatment.

Who grants such exceptions?

The U.S. Food and Drug Administration (FDA) under regulations called 21 Code of Federal Regulations 50.24 specifies the conditions under which an exception from informed consent may be obtained. The Institutional Review Board (IRB) associated with each hospital approves its use locally.

What if patients don't want to participate in this study?

Patients can withdraw from the study at any time by notifying the investigator.

Will patients still receive treatment if they don't want to participate in the study?

Patients will still receive the standard of care if they decline to participate in this study.

What are the potential benefits of participating in the study?

PolyHeme® may increase the likelihood of survival after traumatic injury.
Patients might avoid the risks of blood transfusion.
Patients might avoid a reduction in the function of internal organs that sometimes follows blood transfusion.
This study may help patients in the future.

What are the potential risks of participating in the study?

Rash
Increased blood pressure
Kidney or liver damage
Transmission of hepatitis and HIV viruses
Unforeseen happenings

How much will it cost patients to participate?

There is no charge to the patient to participate in this study. The costs of certain laboratory tests that are required will be paid by the study sponsor.

Will patients get paid to participate?

No, patients will not be paid to participate in this study.

Who is the manufacturer of PolyHeme®?

Northfield Laboratories Inc., Evanston, IL. For more information, visit www.northfieldlabs.com

FOR MORE INFORMATION
OR
TO DECLINE POLYHEME
CONTACT:

Dr. Leonard Weireter
Director of the Shock Trauma Center,
Sentara Norofik General Hospital
Tel. 446-8950

or

Lynn Hopkins RN, MSN, ACNP
Clinical Nurse Coordinator of Surgical,
Emergency and Critical Care Research
Tel. 668-4181

SAVING LIVES

in the city of

NORFOLK, VIRGINIA

Are you a candidate for a new blood substitute in the city of
NORFOLK, VIRGINIA ?

The Department of Surgery at
Eastern Virginia Medical School,
Sentara Norfolk General Hospital and the City
of Norfolk are conducting a research trial using

POLYHEME -
A New Blood Substitute

SENTARA.

EASTERN VIRGINIA
MEDICAL SCHOOL

SAVING LIVES IN THE CITY OF NORFOLK, VIRGINIA

WHAT IS POLYHEME?

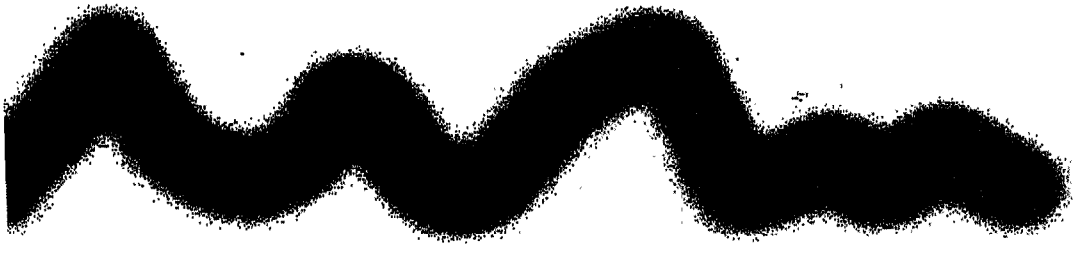
Polyheme is a universally compatible, immediately available, disease free, oxygen carrying fluid developed as a ***blood substitute*** for use in urgent blood loss.

YOU ARE A CANDIDATE FOR POLYHEME IF:

- You are traveling or live in the City of Norfolk, Virginia
- You are involved in a traumatic accident such as a motor vehicle accident, gunshot wound or fall
- You are severely injured and your blood pressure is extremely low

YOU **ARE NOT** A CANDIDATE FOR POLYHEME IF:

- You are pregnant or breastfeeding
- You have objections to receiving a blood substitute
- You have religious beliefs which exclude the administration of blood products



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TRAUMA RESEARCH STUDY
SENTARA NORFOLK GENERAL HOSPITAL
SUMMER 2004-SUMMER 2005

POLY HEME TRAUMA TRIAL
Polyheme - A BLOOD SUBSTITUTE
TREATING PATIENTS IN NORFOLK WITH
THE FOLLOWING CONDITIONS:
Gun Shot Wound
Car Accident
Assault
AND YOU ARE BLEEDING
If you DO NOT want to receive a blood substitute OR
For more information call
Lynn Hopkins ACNP,MSN,RN.
668-4181
or
Leonard Weireter M.D
446-8950

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